

**REMARKS**

Claims 1-20 are pending in this application. Claims 16-20 are presently withdrawn from consideration.

Applicants appreciate the courtesies shown to Applicants' representative by Examiner Kuhns in the May 14, 2007 interview. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

**I. Information Disclosure Statement**

An Information Disclosure Statement (IDS) was filed on July 23, 2004 citing nineteen references. In the Form PTO-1449 returned by the Patent Office with the March 5, 2007 Office Action, references 11-19 were initialed by Examiner Kuhns, but references 1-10 were not initialed.

A copy of the Form PTO-1449 (having only references 1-10) is enclosed herein. Applicants respectfully request Examiner Kuhns to initial references 1-10 on the enclosed Form PTO-1449 and to forward the initialed Form to Applicants' representative listed below.

**II. Rejection Under 35 U.S.C. §112**

Claims 1-15 were rejected under 35 U.S.C. §112, first paragraph, as allegedly being non-enabled by the specification. Specifically, the Patent Office alleges that the recitation that "a solvent for the polymer component is selected for which, on cooling at a rate of 1°C/min, the demixing temperature of a solution of 25% by weight of the polymer component in the solvent is 10 to 70°C above the solidification temperature", as recited in claim 1, is not enabled by the specification. This rejection is respectfully traversed.

Applicants respectfully submit that the selection of a solvent and polymer component combination satisfying the last clause of claim 1 is enabled by the specification and does not require undue experimentation.<sup>1</sup>

First, undue experimentation is not required to determine solvent/polymer component materials satisfying the recited relationship. As recognized by the Patent Office, the test for this property is summarized in paragraph [0050] of the specification. The test is simple and straightforward, and requires no undue experimentation to determine whether a particular polymer component-solvent combination meets the criterion set forth in the final clause of claim 1. The test includes (1) preparing a solution by heating the polymer-solvent mixture until a homogeneous solution is obtained, (2) cooling the homogeneous solution down in a defined manner at a rate of 1°C/min, (3) visually assessing the state of the solution to determine the demixing temperature (phase separation temperature) and the solidification temperature, and (4) determining if the demixing temperature is 10 to 70°C above the solidification temperature.

These conditions of the test are set forth throughout the specification and in claim 1, as originally filed, and provide one of ordinary skill in the art with sufficient guidance for conducting the test to determine the appropriate polymer-solvent mixture for the process for producing an integrally asymmetrical hydrophobic membrane, without undue experimentation. The test is simple and will readily inform one of ordinary skill in the art whether the criteria is met without undue experimentation.

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<sup>1</sup> As set forth in MPEP §2164.01, the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the application coupled with information known in the art without undue experimentation. The test is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. Moreover, the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed (see MPEP §2164.06).

Further, the specification and claims give more specific guidance on the polymer component and solvent materials for use in the process, which clearly enables the practice of the claimed process. For example, contrary to the allegations of the Patent Office, one of ordinary skill in the art of membrane development does not start with any polymer-solvent combination, but starts with a particular polymer, such as a particular polyolefin. The particular polymer selected by one of ordinary skill in the art of membrane development depends upon the desired polymer that the resulting membrane is to be made from. Depending upon the desired application for the resulting membrane, a membrane material for the resulting membrane is known to be required to have specific physico-chemical properties that are necessary for the resulting membrane to perform the desired application. Each desired application may require the resulting membrane to exhibit different physico-chemical properties, such as hydrophilicity/hydrophobicity properties, temperature resistance properties, solvent resistance properties, biocompatibility properties or the like. Thus, one of ordinary skill in the art of membrane development starts with a particular polymer material depending upon the desired application for the resulting membrane or the desired properties to be exhibited by the resulting membrane.

In addition, the specification and claims give much guidance on selection of the appropriate solvent to use with a selected polymer component. For example, the process recited in the present claims is based on a thermally induced phase separation process with liquid-liquid phase separation (see paragraph [0046] of the present application). According to feature a) of claim 1, one of ordinary skill in the art of membrane development selects an appropriate solvent for the polymer to form a system appropriate for such process, wherein the system at elevated temperatures has a range in which it is present as a homogeneous solution, on cooling has a critical demixing temperature, below the critical demixing temperature in the liquid state of aggregation has a miscibility gap, and has a solidification

temperature.<sup>2</sup> Thus, one of ordinary skill in the art is provided with reasonable guidance by the specification and claim 1 with respect to conducting any experimentation to determine an appropriate solvent for the polymer in accordance with feature a) of claim 1.

Thus, only solvents which fulfill the criterion of feature a) of claim 1 have to be tested according to the simple, routine test disclosed in the specification. The number of solvents that must be tested is therefore relatively small or minimal because of the requirement of also satisfying the criterion of feature a) of claim 1.

Applicants also submit that when starting from a particular polymer material depending on the desired application for the resulting membrane, it is routine for one of ordinary skill in the art of membrane development to determine an appropriate solvent as set forth in feature a) of claim 1. Numerous patents have been granted regarding the manufacture of membranes by similar thermally induced phase separation (TIPS) processes with liquid-liquid phase separation. See, for example, U.S. Patent No. 4,564,488 (cited as DE-A-28 22 493 in the present specification) which describes a process for preparation of membranes, and U.S. Patent No. 4,247,498 (cited as DE-C-27 37 745 in the present specification) which relates to microporous bodies produced by using a process with thermally induced liquid-liquid phase separation. Such processes are well known to those skilled in the art of membrane development as basic literature that provides information relating to compatible liquids. Other patents that are related to similar processes and procedures with respect to polymer/solvent selection include U.S. Patent Nos. 4,594,207, 4,957,943, 5,238,618, and 5,238,623, which will be submitted to the Patent Office in a separately filed Information Disclosure Statement.

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<sup>2</sup> Thermally induced phase separation process with liquid-liquid phase separation is well known in the prior art as illustrated in DE-C-27 37 745, DE-A-28 33 493, WO 00/43113 and WO 00/43114 (equivalent to U.S. Patents Nos. 4,247,498, 4,564,488, 6,497,752, and 6,375,876, respectively), each of which were identified in the present specification.

Starting with the procedures disclosed in the above-mentioned patents to find a suitable solvent for the polymer selected to manufacture the desired membrane, i.e., a solvent which satisfies the criterion of feature a) of claim 1, one of ordinary skill in the art merely has to apply the test described in paragraph [0050] of the present specification to select an appropriate solvent which satisfies the criterion of the last clause of claim 1.

Additionally, Applicants submit that the Patent Office's position is inconsistent with previous decisions made by the Patent Office in issuing three other U.S. patents to the Assignee of the present application for similar processes. U.S. Patent No. 6,409,921 relates to a membrane manufacturing process with thermally induced liquid-liquid phase separation (liquid-liquid TIPS process), in which the solvent system consists of compounds A and B, whereby compounds A and B have to meet certain criteria. U.S. Patent No. 6,497,752 (cited as WO 00/43114 in the present specification) discloses a liquid-liquid TIPS process with a solvent system also consisting of compounds A and B, whereby compounds A and B have to meet criteria which are structurally similar to the present claims. U.S. Patent No. 6,375,876 (cited as WO 00/43113 in the present specification) also discloses a process requiring compounds A and B to be determined by criteria of a claimed feature.

The test for determining appropriate compounds A and B for the above-identified patents requires a burden of experimentation that is basically the same as the burden of experimentation for determining an appropriate solvent as set forth in feature a) of claim 1. For these above-identified patents, the Patent Office found that the test for determining appropriate compounds A and B did not require undue experimentation by one of ordinary skill in the art of membrane development. Since the burden of experimentation for these patents should be the same as for the present application, the test for determining an appropriate solvent as set forth in feature a) of claim also does not require undue experimentation by one of ordinary skill in the art of membrane development.

During the May 14, 2007 interview, Examiner Kuhns alleged that one of ordinary skill in the art would not be able to determine which polymer/solvent mixtures would infringe the claims of the present application without having to perform undue experimentation. Contrary to the Examiner's allegations, Applicants submit that whether or not a given polymer/solvent mixture would infringe the claim can simply be determined by applying the test described in paragraph [0050] of the present specification, i.e., a solution of the polymer has to be prepared in the respective solvent at a concentration of 25% by weight which thereafter has to be cooled at a rate of 1 °C/min. If as a result of this test, the criterion of the last clause of claim 1 is fulfilled, the polymer/solvent mixture would infringe claims.

Thus, the present disclosure is enabling to one of ordinary skill in the art to perform the TIPS process with liquid-liquid phase separation for determining an appropriate solvent for a polymer material for the resulting membrane without undue experimentation.

For at least the foregoing reasons, claims 1-15 are enabled. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

### **III. Rejoinder**

Applicants respectfully submit that because claims 1-15 are in condition for allowance for the reasons set forth above, claims 16-20 should be rejoined and similarly allowed as all withdrawn claims depend, directly or indirectly from claim 1, claims 16-20 should be rejoined and similarly allowed. Thus, withdrawal of the Restriction Requirement and rejoinder of claims 16-20 are respectfully requested.

### **IV. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-20 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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WPB:BCA/hs

Attachment:  
Form PTO-1449

Date: June 5, 2007

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